

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1-2. (canceled)

3. (currently amended) A pharmaceutically acceptable inhalation powder in the form of dry, finely divided heat sterilized particles having a mass median diameter (MMD) of less than 10 μm , said dry particles comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof, comprises an asymmetric acetal structure, in which the powder is essentially free of unknown foreign steroids formed from the degradation of the glucocorticosteroid.

4. (previously presented) The powder according to claim 3, said dry powder containing greater than 98.5% by weight of the glucocorticosteroid or ester, acetal, or salt thereof.

5. (canceled)

6. (previously presented) The powder according to claim 3, wherein the glucocorticosteroid or ester, acetal, or salt thereof is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

7. (canceled)

8. (currently amended) A sterile pharmaceutical suspension comprising an aqueous suspension of a pharmaceutically acceptable inhalation powder in the form of finely divided heat sterilized particles, said particles comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof, comprises an asymmetric acetal structure, wherein at least 80% of the particles have a mass median diameter (MMD) of less than 10 μm , and in which the powder is essentially free of unknown foreign steroids formed from the degradation of the glucocorticosteroid.

9. (previously presented) The sterile pharmaceutical suspension according to claim 8, further comprising one or more pharmaceutically acceptable additives, diluents or carriers.

10. (previously presented) The sterile pharmaceutical suspension according to claim 8, comprising at least one additive selected from the group consisting of surfactants, pH regulating agents, chelating agents, agents rendering the formulation isotonic and thickening agents.

11. (previously presented) The sterile pharmaceutical suspension according to claim 8, wherein the concentration of the glucocorticosteroid or ester, acetal, or salt thereof, ranges from about 0.05 to about 20 mg/ml in the formulation.

12. (previously presented) The sterile pharmaceutical formulation according to claim 8, wherein the glucocorticosteroid is an anti-inflammatory glucocorticosteroid.

13. (canceled)

14. (previously presented) The sterile pharmaceutical formulation according to claim 8, wherein the glucocorticosteroid or ester, acetal, or salt thereof is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

15-29. (canceled)

30. (previously presented) A method for treatment of an allergic and/or inflammatory condition of the nose or lungs comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a powder according to claim 3.

31. (previously presented) A method for treatment of chronic obstructive pulmonary disease (COPD), rhinitis or asthma comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a powder according to claim 3.

32. (previously presented) The powder according to claim 3, wherein the particles have a mass median diameter (MMD) of less than 5 μm .

33. (previously presented) The powder according to claim 3, wherein the particles have a mass median diameter (MMD) of less than 1 μm .

34. (previously presented) The powder according to claim 3, said powder comprising greater than 99.2% of the glucocorticosteroid or ester, acetal, or salt thereof.

35. (previously presented) The powder according to claim 3, wherein the glucocorticosteroid is budesonide or ester, acetal, or salt thereof.

36. (canceled)

37. (previously presented) The sterile pharmaceutical formulation according to claim 11, wherein at least 60% of the particles have a mass median diameter (MMD) of less than 4 μm .

38. (previously presented) The sterile pharmaceutical formulation according to claim 8, wherein the concentration of the glucocorticosteroid or ester, acetal, or salt thereof ranges from about 0.1 to about 5 mg/ml.

39. (currently amended) A pharmaceutically acceptable inhalation powder in the form of finely divided particles having a mass median diameter (MMD) of less than 10 μm , said particles being sterilized by heat treatment at a temperature of from 100°C to 130°C and comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof, comprises an asymmetric acetal structure, and in which the powder is essentially free of unknown foreign steroids formed from the degradation of the glucocorticosteroid.

40. (previously presented) The powder according to claim 39, wherein the particles have a mass median diameter (MMD) of less than 5 μm .

41. (previously presented) The powder according to claim 39, wherein the powder is sterilized by heat treatment for no more than 4 hours.

42. (previously presented) The powder according to claim 39, wherein the powder is sterilized by heat treatment at a temperature of about 120°C for no more than 2 hours.

43. (previously presented) A method for treatment of an allergic and/or inflammatory condition of the nose or lungs comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a formulation according to claim 8.

44. (previously presented) A method for treatment of chronic obstructive pulmonary disease (COPD), rhinitis or asthma comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a formulation according to claim 8.

45. (previously presented) The powder according to claim 39, wherein the glucocorticosteroid or ester, acetal, or salt thereof is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

46. (previously presented) The powder according to claim 39, wherein the glucocorticosteroid or ester, acetal, or salt thereof contains less than about 0.5% (w/w) of water before the heat treatment.

47. (previously presented) The powder according to claim 3, wherein the asymmetric acetal structure comprises 16 α ,17 α -butylidenedioxy.

48. (previously presented) The powder according to claim 8, wherein the asymmetric acetal structure comprises 16 α ,17 α -butylidenedioxy.

49. (previously presented) A pharmaceutically acceptable powder in the form of heat sterilized, dry, finely divided particles comprising budesonide, rofleponide or rofleponide palmitate, or ester, acetal, or salt thereof.

50. (previously presented) A sterile pharmaceutical formulation comprising a pharmaceutically acceptable powder in the form of heat sterilized, dry, finely divided particles and comprising budesonide, rofleponide or rofleponide palmitate, or ester, acetal or salt thereof.

51. (previously presented) A pharmaceutically acceptable powder in the form of heat sterilized, dry, finely divided particles, said powder being sterilized by heat treatment at a temperature of from 100°C to 130°C and comprising budesonide, rofleponide or rofleponide palmitate, or ester, acetal or salt thereof.

52. (previously presented) A pharmaceutically acceptable powder in the form of heat sterilized, dry, finely divided particles comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof comprises an asymmetric acetal structure and in which the powder is essentially free of unknown foreign steroids formed from the degradation of the glucocorticosteroid.

53. (canceled)

54. (currently amended) A pharmaceutically acceptable suspension comprising heat sterilized, finely divided particles comprising budesonide, rofleponide or rofleponide palmitate, or ester, acetal or salt thereof, combined with a pharmaceutically acceptable additive.

55. (canceled)

56. (currently amended) The powder of claim 51, wherein the particles hashave essentially the same ~~pharmacological activity and physico-chemical properties~~, chemical purity and physical form as the particles before sterilization.

57. (new) A pharmaceutically acceptable inhalation powder in the form of dry, finely divided heat sterilized particles having a mass median diameter (MMD) of less than 10 μm , said dry particles comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof, comprises an asymmetric acetal structure, in which the powder contains not more than 0.38 % known and unknown foreign steroids formed from the degradation of the glucocorticosteroid.

58. (new) A sterile pharmaceutical suspension comprising an aqueous suspension of a pharmaceutically acceptable inhalation powder in the form of finely divided heat sterilized particles, said particles comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof, comprises an asymmetric acetal structure, wherein at least 80% of the particles have a mass median diameter (MMD) of less than 10 μm , and in which the powder contains not more than 0.38 % known and unknown foreign steroids formed from the degradation of the glucocorticosteroid.

59. (new) A pharmaceutically acceptable inhalation powder in the form of finely divided particles having a mass median diameter (MMD) of less than 10 μm , said particles being sterilized by heat treatment at a temperature of from 100°C to 130°C and comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof, comprises an asymmetric acetal structure, and in which the powder contains not more than 0.38 % known and unknown foreign steroids formed from the degradation of the glucocorticosteroid.

60. (new) A pharmaceutically acceptable powder in the form of heat sterilized, dry, finely divided particles comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof comprises an asymmetric acetal structure and in which the powder contains not more than 0.38 % known and unknown foreign steroids formed from the degradation of the glucocorticosteroid.

61. (new) The powder according to claim 3 in which the powder contains 0.18% or less of unknown foreign steroids formed from the degradation of the glucocorticosteroid.

62. (new) The suspension according to claim 8 in which the powder contains 0.18% or less of unknown foreign steroids formed from the degradation of the glucocorticosteroid.

63. (new) The powder according to claim 39 in which the powder contains 0.18% or less of unknown foreign steroids formed from the degradation of the glucocorticosteroid.

64. (new) The powder according to claim 54 in which the powder contains 0.18% or less of unknown foreign steroids formed from the degradation of the glucocorticosteroid.